

REMARKS

The foregoing amendments were made to correct for typographical errors in the originally submitted claims. No new matter has been added. Claims 1-69 are the subject of the Office Action. Applicants acknowledge with appreciation that claims 34-69 have been allowed. In the Office Action, the Examiner rejected claims 1-33. Applicants traverse the Examiner's rejections as set forth below, and request that the Examiner consider the following amendments, which are being made to correct typographical errors, and remarks. Applicants respectfully submit that the amendments and remarks demonstrate that all claims 1-69 are in condition for allowance.

35 U.S.C. § 102(b) Rejection Overcome

The Examiner rejected claims 1-33 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,777,095 ("the '095 patent") because this reference allegedly discloses a non-pathogenic microorganism used for live vaccines. The '095 patent suggests that non-pathogenicity may be obtained by alteration or modification by mutagenization, chemical, enzymatic or heat treatment, or by another equivalent treatment resulting in a modification of the outer surface protein. The Examiner further stated that the nuclear components of the non-pathogenic microorganism are presumed to be intact.

Applicants respectfully traverse the rejection. The '095 patent neither teaches nor suggests the invention of 1-33. The subject invention is directed to a composition of matter, and methods for preparing the composition, that is useful as reliable positive control materials for the detection of virus by nucleic acid amplification techniques. Thus, the claims are directed to a purified microorganism comprising surface proteins and substantially intact nuclear components, wherein one or more surface proteins have been irreversibly modified such that the microorganism is thereby rendered nonpathogenic. By preserving the nuclear contents, but rendering the material nonpathogenic, the compositions of the invention can be readily stored and handled and will be detectable in assays for the nucleic acid content of the virus. The invention also provides a method for producing a non-pathogenic microorganism comprising providing a purified microorganism comprising surface proteins and intact nuclear components and irreversibly modifying one or more surface proteins while leaving the nuclear components substantially unmodified such that the microorganism is thereby rendered nonpathogenic.

The cited reference does not disclose or suggest the invention recited in claims 1-33. The '095 patent, in particular the section cited by the Examiner, discusses isolated DNA molecules, vectors containing those molecules, and a method of detecting *Borrelia burgdorferi* in an animal or human. Moreover, the '095 patent does not specifically describe the use of a purified microorganism. Applicants' claims recite a purified microorganism and methods for making a purified microorganism useful as a control material. Accordingly, because the '095 patent does not teach the claimed subject matter, it does not anticipate claims 1-33.

35 U.S.C. § 103(a) Rejection Overcome

The Examiner rejected claims 1-33 under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '095 patent. The Examiner relied on the '095 patent for the reasons noted above, *i.e.*, for allegedly teaching inactivation of an intact pathogenic microorganism to obtain a non-pathogenic live vaccine. The Examiner maintains that, given the '095 patent, one of ordinary skill in the art would allegedly have been motivated to use various chemical compounds and enzymatic treatments and various microorganisms to obtain the claimed invention.

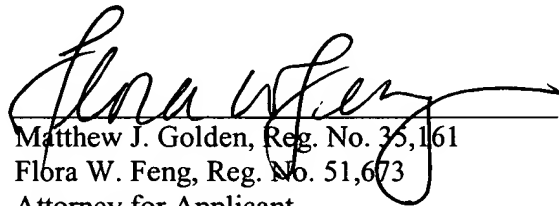
Applicants respectfully traverse the rejection. Applicants maintain that the '095 patent neither teaches nor suggests the claimed invention. There is no teaching or suggestion in the '095 patent of production of a purified microorganism that is rendered nonpathogenic but that retains substantially intact nuclear components. The '095 patent does not teach production of a control material having intact nuclear components but suggests the production of a live vaccine by modifying the outer surface protein of a microorganism. Making a vaccine is not the same as making a control material. To make a live vaccine, it is desirable to alter the DNA of the microorganism so that it will not replicate, yet leave the surface antigens sufficiently intact for a patient to produce antibodies against it. Furthermore, inactivation of a microorganism is only generally described. One skilled in the art would not be motivated to use the techniques described on a purified microorganism to make a control material with substantially intact nuclear material. In addition, the '095 patent is similar to the art distinguished in the background section of the present application. Accordingly, Applicants maintain that the cited reference does not suggest the claimed invention.

SUMMARY

On the basis of the above, Applicants respectfully submit that the Examiner's rejections have been traversed and that the pending claims 1-69 are in condition for allowance. If there are any questions regarding these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Dated: September 23, 2003



Matthew J. Golden, Reg. No. 35,161

Flora W. Feng, Reg. No. 51,673

Attorney for Applicant

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
and POPEO, P.C.

Chrysler Center

666 Third Avenue

New York, NY 10017

Telephone: (212) 935-3000

Telefax: (212) 983-3115